

**REMARKS**

Applicant submits this Amendment together with a Request for Continued Examination (RCE) in response to the final Office Action mailed on March 30, 2010, and the Advisory Action mailed on September 9, 2010.

In the Action, the Examiner rejected claims 31-33 and 38-44 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In addition, the Examiner rejected claims 31-33 and 38-44 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Walinsky (U.S. Patent No. 5,575,771) in view of Osborne et al. (U.S. Patent No. 5,690,642). The Examiner made the rejections final.

By this Amendment, Applicant amends claims 31, 38-40, 43, and 44, and cancels claims 33 and 42. Claims 31-32, 38-41, and 43-44 are currently pending. Of these claims, claims 31 and 40 are independent.

**35 U.S.C. § 112, First Paragraph, Rejection**

Applicant respectfully traverses the Section 112, first paragraph, rejections of claims 31-33 and 38-44. In formulating these rejections, the Examiner states that "[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." See Office Action at page 2.

Further, the Examiner contends that there is insufficient support in the Applicant's specification for the "limitations stating that the anchor limits the balloon's expansion in

comparison with the expansion in an unconstrained portion in which the anchor element is not present when the balloon changes from its contracted to its deployed state.” Id.

Applicant respectfully disagrees.

In the Advisory Action mailed on September 9, 2010, the Examiner contends:

The current claims include limitations stating that the anchor limits the balloon's expansion in comparison with the expansion in an unconstrained portion. While it appears that the balloon may be capable of altering the shape of an expanded balloon, the Applicant has not provided support from the specification that states that the balloon would limit the balloon's expansion.

See Page 2 of the Advisory Action. Applicant respectfully disagrees.

For the purposes of this response, Applicant understands the above-captioned Examiner's contention to be directed to the anchor (not the balloon) being capable of altering the shape of the expanded balloon, and that the anchor (not the balloon) would limit the balloon's expansion. If the Applicant's understanding is incorrect, the Examiner is kindly requested to contact the undersigned as soon as possible at (202) 408-4221.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter at the time the application was filed. See M.P.E.P. § 2163. If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of the filing, even if every nuance of the claims is not explicitly described in the specification, then the written description requirement is met. *In re Alton*, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). The written description requirement may be satisfied using words, structures, figures, diagrams, and formulas. See M.P.E.P. § 2163.02 (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966

(Fed. Cir. 1997)). Indeed, in some circumstances, "drawings alone may provide a 'written description' of an invention as required by § 112." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1565, 19 USPQ2d 1111, 1118 (Fed. Cir. 1991).

Additionally, "[t]he examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims." See M.P.E.P. § 2163(III)(A). In rejecting claims under Section 112, first paragraph, the examiner "must set forth express findings of fact regarding the [] analysis which support the lack of written description conclusions." *Id.* In addition to identifying the claim limitation at issue, these findings should "[e]stablish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed." *Id.* (Emphasis added.)

Moreover, "an applicant is not limited to the nomenclature used in the application as filed." See M.P.E.P. § 608.01(o). Instead, it is only required that the terminology of the claims "find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." *Id.* Indeed, as alluded to above, claims may find descriptive basis in the original disclosure, which includes "the specification with original claims and drawings, as filed." See M.P.E.P. § 608.

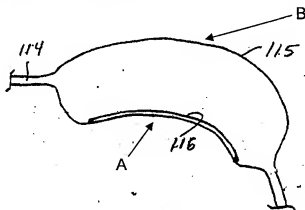
As an initial matter, Applicant notes that the Office Action does not provide the required findings of fact to support the Section 112, first paragraph, rejection of claims 31-33 and 38-44. Specifically, the Examiner has failed to provide any reasons why a

person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed, as required by Section 2163(III)(A) of the M.P.E.P. Instead, the Action conclusorily asserts that the specification does not provide support for "limitations stating that the anchor limits the balloon's expansion in comparison with the expansion in an unconstrained portion in which the anchor element is not present when the balloon changes from its contracted to its deployed state." Office Action at page 2. In the event the Examiner maintains the Section 112, first paragraph, rejection of claims 31-33 and 38-44, the Examiner is requested to provide the necessary findings of fact and reasons required by Section 2163(III)(A) of the M.P.E.P.

Notwithstanding the above, the subject matter of the pending claims is adequately supported by the originally-filed disclosure. Figures 17A'-17B' and the corresponding written disclosure describe a balloon 115 having an anchor element 116 affixed to its interior surface. As specifically shown in Figures 17A'-17B', anchor element 116 limits expansion (or, in the case of claim 40, restrains expansion) of the surface it is affixed to when compared to the degree of expansion experienced by the opposing surface or side of balloon 115. Stated differently, when balloon 115 changes from its contracted state (shown in Fig. 17A') to its deployed state (shown in Fig. 17B'), the surface of balloon 115 to which anchor element 116 is affixed undergoes limited expansion (or, in the case of claim 40, restrained expansion) when compared to the expansion experienced by the opposite side surface, which does not include an anchor element. One of ordinary skill in the art therefore would understand that the application disclosure, as a whole, provides adequate written description support for "limitations

stating that the anchor limits the balloon's expansion in comparison with the expansion in an unconstrained portion in which the anchor element is not present when the balloon changes from its contracted to its deployed state."

With specific regard to the Examiner's contentions in the Advisory Action, Applicant refers to the following annotated reproduction of Fig. 17B':



*Fig. 17B'*

As an initial matter, Applicant once again notes that an application's drawings alone may provide a written description of an invention. Next, as clearly shown above, the wall A of balloon 115 which is affixed to anchor element 116 experiences limited expansion as compared to the opposing wall B. It is this very difference in expansion that causes the balloon to adopt the predetermined shape depicted in Fig. 17B' and discussed in the corresponding written description. Thus, contrary to the Examiner's contentions, the specification does provide support for the claimed subject matter.

For at least these reasons, Applicant respectfully requests reconsideration and the withdrawal of the Section 112, first paragraph, rejection of claims 31-33 and 38-44.

**35 U.S.C. § 103(a) Rejection**

Applicant respectfully traverses the Section 103(a) rejection of claims 31-33 and 38-44 over Walinsky and Osborne et al. Neither reference, taken alone or in combination, teaches or suggests each and every element of independent claims 31 and 40. In particular, the applied references at least fail to disclose the claimed combination including a balloon having contracted and deployed states and an interior surface defining an expandable chamber, and an anchor element that limits (or, in the case of claim 40, restrains) expansion of the balloon in a constrained portion, wherein “an entirety of the anchor element is disposed within the expandable chamber of the balloon.”

Walinsky discloses a balloon catheter with an external guidewire 40. As shown in, for example, Fig. 1, catheter 10 includes an elongate flexible body 12a and a balloon 24. In addition, catheter 10 includes a guidewire 40 extending “over the *exterior* of the balloon when the balloon is inflated.” Col. 5, ll. 15-16. (Emphasis added.). In Fig. 7a, Walinsky discloses an arrangement similar to that of Fig. 1, but in which an interior surface of balloon 24 is attached to perfusion body portion 12. As a result, the portion of balloon 24 attached to body portion 12 is precluded from expanding. See col. 6, ll. 31-38.

In the final Office Action, the Examiner alleges that the guidewire 40 of Walinsky corresponds to the claimed anchor element. See Office Action at page 3. Even if guidewire 40 may be construed to limit or restrain expansion of balloon 24, which Applicant does not concede, an entirety of guidewire 40 is not disposed within the expandable chamber of balloon 24, as required by claims 31 and 40. Indeed, as

explicitly depicted in, for example, Figure 1, guidewire 40 extends over an exterior of balloon 24.

In the Advisory Action, the Examiner contends:

The examiner is interpreting the claim language "disposed within the balloon" to mean that the anchor is surrounded by the balloon. Walinsky shows in Figure 7A that anchor element 40 is surrounded by the outer surface of balloon 24, thus meeting the claims' limitations.

Page 2 of the Advisory Action. Applicant respectfully disagrees.

As an initial matter, even if Fig. 7A of Walinsky could be construed to depict the outer surface of balloon 24 "surrounding" guidewire 40, which Applicant does not concede, one of ordinary skill in the art would recognize that guidewire 40 is not disposed within the expandable chamber of balloon 24. That is to say, merely surrounding anchor element with the exterior of balloon 24 does not dispose anchor element within the expandable chamber of balloon 24.

Nonetheless, even if the Examiner maintains that guidewire 40 is disposed "within the balloon," an entirety of guidewire 40 is not disposed within the expandable chamber of the balloon, as required by the independent claims. Indeed, as clearly shown in Fig. 7a, portions of guidewire 40 extend past the proximal and distal ends of balloon 24.

Accordingly, Walinsky fails to teach each and every element of amended independent claims 31 and 40.

The Examiner has relied on Osborne et al. solely for the alleged teaching of utilizing "balloon catheters in the delivery of stent in columns 1 and 2 in order to deliver a contracted stent to its treatment location and expand the stent to meet the dimensions

of the treatment site.” Office Action at page 3. This teaching fails to overcome the above-described deficiency of Valinsky. Thus, the Examiner’s proposed combination of Valinsky and Osborne et al. does not suggest each and every limitation of independent claims 31 and 40, and, therefore, claims 31 and 40 and their dependent claims are allowable over these references.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the Section 103(a) rejection of claims 31-33 and 38-44 over Valinsky and Osborne et al.

### **Conclusion**

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicants is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

If the Examiner wishes to discuss this application, he is invited to contact the undersigned at (202) 408-4221.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of the application, and the timely allowance of the pending claims.



Please grant any extensions of time required to enter this Amendment, and  
charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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GARRETT & DUNNER, L.L.P.

Dated: September 30, 2010

By: 

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